

REMARKS

Claims 1-73 were originally pending in the present application. After restriction and election, however, Claims 24-29, 32-44, 46, 51-53, 56, 60, 61, and 68-73 have been withdrawn from consideration as drawn to non-elected species. With the present amendment, claims 1, 2, 7-9, 11, 15, 16, 19, 20-22, 30, 45, 48, 57 and 62 have been amended and claims 6, 12, 18, 23 and 46 have been canceled. As a result, claims 1-5, 7-11, 13-17, 19-22, 30, 31, 45, 47-50, 54, 55, 57-59, and 62-67 are at issue in the case.

35 U.S.C. §102(b) Rejections

In paragraph 3 of the Office Action, the Examiner rejected claims 1, 2, 4, 6-14, 16-19, 21, 57-59, 62, 66 and 67 under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,723,086 to Bassuk et al. ("Bassuk").

In paragraph 4 of the Office Action, the Examiner rejected claims 1-3, 5-12, 16, 18-20, 22 and 57-59 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,733,256 to Costin ("Costin").

In paragraph 5 of the Office Action, the Examiner rejected claims 1, 2, 6, 11-19, 23, 30, 31, 45, 47-50, 54, 55, 57, 62, 63 and 67 under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,692,481 to Guerrero ("Guerrero").

The Examiner has rejected all pending claims as anticipated by one of Bassuk, Costin or Guerrero. The Applicants respectfully traverse these rejections and request the Examiner to reconsider in light of the remarks herein.

In order for a reference to act as a § 102 bar to patentability, the reference must teach each and every element of the claimed invention. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). Without the required teaching of "each and every element" as set forth in the claims, it is improper for the Examiner to continue such rejections under §102. Applicants submit that the cited references fail to provide the necessary teaching of each and

every element of the rejected claims as amended and, therefore, the Examiner's current rejections under 35 U.S.C. 102(b) are not supportable.

Independent Claims 1, 11, 16, 30, 57 and 62 each contain the element "a "controller operably connected to the MEMS element, wherein the controller is detachable from the MEMS element." Similarly, claim 15 requires, a "controller operably connected to the MEMS pump, wherein the controller is detachable from the MEMS pump." Independent claims 45 and 48 have a similar element to claim 15. Thus, these independent claims require, among other things, a controller that is detachable from the MEMS element. The remaining dependent claims are likewise limited.

As shown for example in FIGS. 2 and 3 of the present application, the controller 38 is connected to the MEMS element such as a MEMS pump. The controller 38 is used to govern operational characteristics of the MEMS element. The controller 38 shown is detachable from the MEMS element by a variety of methods including the plug type connection shown in the figures. (Specification, pg. 5, lns. 1-15.) The disclosed detachable connection allows the controller 38 to be, in certain embodiments, a reusable, durable component of the system while other components of the system may be disposable. (Specification, pg. 4, lns 22-27.) For example, the specification states at page 7, lines 17-21:

In a preferred embodiment shown in FIG. 3, the MEMS pump element 52 would contain electrical connectivity to enable interface to the durable controller 38 that would control the pump 52 to maintain a desired flow rate. The MEMS pump element 52 can be disposed of with the rest of the disposable components of [the] line-set. The electronics of the controller 38 and any type of case or user's interface would be maintained as a durable, reusable system.

Accordingly, the disclosed detachable connection between the controller and the MEMS element allows the controller to be reused with additional system components. The cited references do not disclose or suggest a controller that is detachable from the MEMS element. Accordingly, the Applicants traverse the Examiner's rejection of the pending claims.

Bassuk is directed to a remote controlled transdermal medication delivery device 20. Bassuk discloses the device 20 as having a control module 24 that utilizes a MEMS-based valve chip 64 (FIG. 3). Bassuk specifies that the device 20 includes a controller 92 for controlling flows of medication through the valve chip 64 (Col. 6, lns. 7-14). As further shown in FIG. 3 and which can be appreciated from FIGS. 1, 2 and 4, the controller 92 is housed within the control module 24 and is connected to other components of the device 20. Contrary to the Examiner's conclusion in paragraph 3 of the Office Action, Bassuk does not disclose that the controller 92 is detachable from the MEMS element, the MEMS-based valve chip 64. In addition, the Examiner has not indicated or otherwise cited any disclosure in Bassuk showing how the controller is detachable from the MEMS-based valve chip 64. Bassuk lacks any such disclosure. Furthermore, Bassuk contains no suggestion or other teaching for the controller 92 to be detachable from the MEMS element. Accordingly, Bassuk cannot anticipate or render obvious the pending claims.

Costin is directed to an integrated phacoemulsification system used during cataract surgery. The disclosed system allows direct measurement and control of fluid dynamics within the anterior chamber of the human eye during phacoemulsification surgery. As shown for example in FIGS. 4 and 8 of Costin, the system provides an infusion conduit to a surgical handpiece assembly. Pressure/flow sensors are associated with the infusion conduit. Costin specifies that the sensors are pressure sensors and flow sensors. Costin discloses a microprocessor control 102 attached to the system. Contrary to the Examiner's conclusion in paragraph 4 of the Office Action, Costin does not disclose that the controller 102 is detachable from the MEMS sensors. In addition, the Examiner has not indicated or otherwise cited any disclosure in Costin showing how the controller is detachable from the MEMS sensors. Costin lacks any such disclosure. Furthermore, Costin contains no suggestion or other teaching for the controller 102 to be detachable from the MEMS sensors. Accordingly, Costin cannot anticipate or render obvious the pending claims.

Guerrero is directed to a method and apparatus for improving vision in an amblyonic eye. Guerrero discloses a drug delivery device 150 that delivers medication to a patient's eye. As

shown in FIG. 3, the drug delivery device 150 is a unit that is worn, for example, on a patient's eyeglasses. FIG. 4 discloses a schematic view of the drug delivery device 150. The device 150 has a drug reservoir 190 that contains the drug to be administered. A pump 200 conveys the drug from the reservoir 190 to an appropriate delivery canula such as a length of flexible tubing 90. Guerrero indicates that the pump 200 may be a MEMS pump. The operation of the pump is controlled by pump-controlled circuitry 220. The settings of the circuitry 220 are adjusted via the pump control interface 230. FIG. 4 shows these elements contained within a case 180. Contrary to the Examiner's conclusion in paragraph 5 of the Office Action, Guerrero does not disclose that the controller 220 is detachable from the pump 200. In addition, the Examiner has not indicated or otherwise cited any disclosure in Guerrero showing how the controller is detachable from the MEMS pump. Guerrero lacks any such disclosure. Furthermore, Guerrero contains no suggestion or other teaching for the controller 220 to be detachable from the pump 200. Accordingly, Guerrero cannot anticipate or render obvious the pending claims.

Thus, there is no disclosure or suggestion of a detachable controller in any of the cited references, Bassuk, Costin or Guerrero. Accordingly, Applicants submit that independent claims 1, 11, 15, 16, 30, 45, 48, 57 and 62 are patentably distinct over the cited references. Applicants respectfully request the Examiner to withdraw the rejections.

Claims 2-5, 7-10, 13-14, 17, 31, 47, 49, 50, 54, 55, 58, 59, and 63-67 are dependent on at least one of the discussed independent claims. In accordance with 35 U.S.C. 112, fourth paragraph, each of these claims is considered to "incorporate by reference all the limitations of the claim to which it refers." Therefore, without more, the dependent claims should be considered to distinguish over the cited references for the same reasons as discussed above. Accordingly, Applicants submit that the dependent claims are patentably distinct over the cited references.

Claim 19 is directed to an intravenous-type infusion system. The claimed system requires, among other things, a length of medical grade IV tube having a first end connected to an IV container and a second end connected to an access device adapted to be connected to a

body, the tube having a MEMS pump attached thereon, wherein the MEMS pump pumps fluid contained in the IV container through the access device.

None of the cited references are directed to an intravenous-type infusion system. As previously discussed, Bassuk is directed to a system designed to be worn by an ambulatory patient. As shown in FIG. 3 in Bassuk, the medication containers are vacuum-sealed tubes 62 (Col. 5, lns. 12-14). Bassuk does not disclose or suggest an IV container as required by claim 19. In addition, Bassuk discloses a MEMS-based valve chip 64 rather than a MEMS pump attached to an IV tubing as required by claim 19. Similarly, Costin does not disclose or suggest an IV container. Costin further only discloses MEMS sensors rather than a MEMS pump attached to an IV tubing as required by claim 19. Finally, Guerrero does not disclose or suggest an IV container as required by claim 19. Guerrero discloses a small container that is housed within a case 180 that may be carried by a patient's eyeglasses. Accordingly, Applicants submit that claim 19 is patentably distinct over the cited references.

Claim 20 depends from claim 19 and requires, among other things, a controller operably connected to the MEMS pump, wherein the controller is detachable from the MEMS pump. For the reasons discussed above, Applicants submit that claim 20 is patentably distinct over the cited references.

Claims 21 and 22 depend from claim 19 and include all of the elements of Claim 19. For the reasons stated with respect to claim 19, Applicants submit that claims 21 and 22 are patentably distinct over the cited references.

35 U.S.C. §103 Rejections

In paragraph 6 of the Office Action, the Examiner rejected claims 64 and 65 under 35 U.S.C. 103(a) as being unpatentable over Bassuk in view of Costin.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art

reference(s) must teach or suggest all of the claim limitations. The examiner bears the initial burden on factually supporting any *prima facie* conclusion of obviousness. See MPEP § 2142; *In re Vaeck*, 20 USPQ.2d 1438 (Fed. Cir. 1991).

As an initial ground for overcoming the rejection, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because there is no suggestion or motivation to combine Bassuk and Costin as suggested by the Examiner. Even though both patents are directed to medical systems, the Examiner has still failed to cite to a specific disclosure in either reference that would have given one the motivation to combine them as proposed by the Examiner. Consequently, the proposed combination cannot establish a *prima facie* case of obviousness with respect to the claims.

In addition, Claims 64 and 65 depend from claim 62 and include all of the elements of claim 62. For the reasons discussed above with respect to claim 62, Applicants submit that claims 64 and 65 are patentably distinct over the proposed combination of Bassuk and Costin.

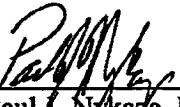
CONCLUSION

In light of the above amendments and remarks, Applicants believe the pending claims are now in condition for allowance. Reconsideration of these claims is respectfully requested. Applicants understand that should any generic claims be finally held allowable, then the species of the withdrawn claims will be considered allowable as well.

If it would expedite the progress of this Application through the examination process, the Examiner is requested to call the undersigned attorney.

Respectfully submitted,

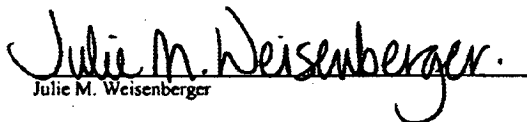
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